MAIL STOP APPEAL BRIEF – PATENTS
Attorney Docket No.: A100001U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

ASIUS et al.		Confirmation No.	6859
Application No.	10/542,544	Group Art Unit:	1619
Filing Date:	July 18, 2005	Examiner:	T. Kassa
Title:	**CERAMIC-BASED INJECTABLE IMPLANTS WHICH ARE USED TO FILL WRINKLES, CUTANEOUS DEPRESSIONS AND SCARS, AND PREPARATION METHOD THEREOF**		

APPEAL BRIEF

This is an appeal to the Board of Patent Appeals and Interferences from the decision of Examiner Tigabu Kassa, mailed August 5, 2010, finally rejecting claims 38-69. Appellants filed a Notice of Appeal on January 5, 2011. This Appeal Brief is due two months from the time the Notice of Appeal is filed. Therefore this Appeal Brief is timely filed.

1. Table of Contents

2. Real Party in Interest

The real party in interest in this appeal is STEIFEL LABORATORIES, INC.

3. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

4. Status of Claims

The status of the claims, upon filing of this Appeal Brief, is as follows:

Claims cancelled: 1-33, 35

Claims withdrawn from consideration but not cancelled: 34, 36 and 37

Claims pending: 34 and 36-69

Claims objected to: None

Claims allowed: None

Claims rejected: 38-69

The claims on appeal are claims 38-69.

5. Status of Amendments

Appellants filed a Preliminary Amendment on July 18, 2005 cancelling claims 1-13 and new claims 14-37 were added.

Appellants filed a Response and Amendment on January 19, 2010, in which claims 14-33 and 35 were cancelled, claims 34, 36 and 37 were withdrawn, and new claims 38-69 were added. The Examiner subsequently issued a final Office Action dated August 5, 2010, in which the new claims were entered and new grounds for rejection made. The claims listed in the claims appendix, Appendix A, herein incorporate the new claims presented in the aforementioned Response and Amendment.

6. Summary of Claimed Subject Matter

Pending independent claim 38 is directed to a resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid, wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months and have a size of from 10 to 80 μm, said ceramic compound is tricalcium phosphate (βTCP) and has a specific surface area of from 0.5 m^2/g to 100 m^2/g, and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties. Bases for claim 38 may be found throughout the specification and claims as originally filed, for example, at page 8, lines 24-37; page 10, lines 13-19; and page 10, line 29 through page 11, line 10.

The second and final pending independent claim, claim 55, is directed to a resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid, wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months, have a size of from 10 to 80 μm, and are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%, said ceramic compound is tricalcium phosphate (βTCP), and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties. Bases for

claim 55 may be found throughout the specification and claims as originally filed, for example, at page 8, lines 24-37; page 10, lines 13-19; and page 10, line 29 through page 11, line 10.

7. Grounds of Rejection to be Reviewed on Appeal

A. Rejection of claims 38-46, 49-51 and 54 under 35 U.S.C. §103(a)

Whether the identified claims are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 7,060,287 to Hubbard et al., in view of U.S. Patent No. 6,451,059 to Janas et al.

B. Rejection of claims 38, 47 and 48 under 35 U.S.C. §103(a)

Whether the identified claims are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 7,060,287 to Hubbard et al., in view of U.S. Patent No. 6,451,059 to Janas et al. and U.S. Patent No. 4,373,217 to Draenert.

C. Rejection of claims 38 and 51-53 under 35 U.S.C. §103(a)

Whether the identified claims are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 7,060,287 to Hubbard et al., in view of U.S. Patent No. 6,451,059 to Janas et al., and U.S. Patent No. 7,019,192 to Gertzman et al.

D. Rejection of claims 55-66 and 69 under 35 U.S.C. §103(a)

Whether the identified claims are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 7,060,287 to Hubbard et al., in view of U.S. Patent No. 4,373,217 to Draenert.

E. Rejection of claims 55 and 66-68 under 35 U.S.C. §103(a)

Whether the identified claims are unpatentable under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 7,060,287 to Hubbard et al., in view of U.S. Patent No. 7,019,192 to Gertzman et al.

8. Argument

A. Rejection of claims 38-46, 49-51 and 54 under 35 U.S.C. §103(a)

Appellants respectfully submit that the rejection of the identified claims as obvious over Hubbard et al. in view of Janas et al. is improper and should be reversed. Appellants respectfully submit that Hubbard et al. and Janas et al. do not render Appellants' claims 38-46, 49-51 and 54 obvious for at least the following reasons.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under 35 USC § 103 by: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of non-obviousness.

Furthermore, to establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to

identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Also, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

With regard to motivation to combine references, **MPEP 2143** discusses the requirements of a *prima facie* case of obviousness. First, there must be some suggestion or motivation to combine the reference teachings or to modify the reference, and second, there must be a reasonable expectation of success. Finally, the prior art reference or references, when properly combined, must teach or suggest all the claim limitations.

Regarding motivation to properly combine or modify references, a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there can be no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference. See **MPEP 2143.01.**

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. Likewise, whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. provide any indication that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*, or provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

Hubbard et al. teach a permanent, biocompatible material for soft tissue augmentation comprising a matrix of smooth, round, substantially spherical particles of a biocompatible ceramic material, where the ceramic material can be homogeneously suspended in a biocompatible, resorbable lubricious gel carrier comprising a polysaccharide. Hubbard et al. generally describes βTCP as a potential ceramic material which may be contained in the implant compositions disclosed therein, and each of hyaluronic acid and xanthan gum as a potential polysaccharide that can be added to the composition.

The implants of Hubbard et al. are of a ***permanent*** nature and preferably employ hydroxyapatite (HAP). Hubbard et al. teach HAP as being highly compatible to tissue and ***substantially nonresorbable***, thereby rendering the ceramic augmentation material permanent and repetitious augmentations unnecessary. *See*, Hubbard et al., col. 4, line 22 and col. 5, lines 47-52.

Likewise, the teachings of Hubbard et al. regarding hyaluronic acid and xanthan gum for use as potential polysaccharides are incomplete in comparison to the instantly claimed subject matter. Specifically, Hubbard et al. do not teach the use of a combination of these two materials, i.e. hyaluronic acid-based compounds and thixotropic compounds. Hubbard et al. provide no compositions containing hyaluronic acid or a combination of any two or more polysaccharides.

Further, Hubbard et al. fails to teach the specific surface area of the ceramic compound, as well as the amounts of the microparticles according to the present claims.

Thus, with respect to the teachings of Hubbard et al., Appellants note the following:

- there is a clear teaching away from biodegradability/degradation due to the ***permanent*** nature of the implants taught therein;
- no biodegradability or time period for degradation is described for ßTCP (which is consistent with the permanence of the implants taught);
- no combinations of hyaluronic acid with a biodegradable thixotropic compound with pseudoplastic properties (such as a polysaccharide) are taught; and
- no specific surface area or overall amount of the ceramic compound is taught.

Janas et al. teach a hard tissue scaffold comprising resorbable ceramic fibers. Janas et al. is cited by the Examiner to cure one of the deficiencies of Hubbard et al., namely the lack of any teaching with respect to particle surface area. In this regard, Janas et al. teach particles of ceramic tricalcium phosphate ($Ca_3(PO_4)_2$), with a BET surface area of 1.708 m^2/g. *See*, Example 1.

However, this teaching is taken out of context of the broader teachings of Janas et al. Specifically, according to Janas et al., the tricalcium phosphate particles have an ***initial surface area*** of 1.708 m^2/g. However, these particles are then used to ***prepare ceramic fibers and scaffolds*** suitable for use in bone replacement, which is the entire object of the teachings of Janas et al.

Accordingly, neither Hubbard et al. nor Janas et al. teach a resorbable implant comprising a ceramic compound that "has a specific surface area of from 0.5 m^2/g to 100 m^2/g."

Appellants respectfully submit that the introduction of the teachings of Janas et al. to supplement the teachings of Hubbard et al. fails to remedy the shortcomings thereof and therefore fails to establish a *prima facie* case of obviousness against claims 38-46, 49-51 and 54. In the first instance, the Examiner's proposed reason for introducing Janas et al., i.e. the teaching of surface area, is not commensurate with the scope of the instant claims. Specifically, the particles of Janas et al. are in no way used as are the presently claimed particles and are thus not present in the product of Janas et al. in the same form as recited in the instant claims.

Furthermore, both Hubbard et al. and Janas et al. are directed to ***permanent*** tissue modification. Thus, the instantly claimed microparticles capable of biodegrading within a period of 2 to 36 months from implantation are clearly not shown by this combination of references. In part, it is the large surface area of the instant microporous ceramic particles (i.e., 0.5 m^2/g to100 m^2/g) that affords the ability of the presently claimed implant to be bioresorbable. In contrast, the particles of Hubbard et al. are smooth and non-porous, as well as round and substantially spherical. Appellants submit that while the technologies taught in Hubbard et al. and Janas et al. are *generally* related to the claimed subject matter, there is nothing in either which would lead one of ordinary skill in the art to modify the teachings of these two references relating *entirely* to permanent tissue repair to arrive at the instantly claimed subject matter relating to bioresorbable implants.

Thus, the combination of Hubbard et al. and Janas et al. fails to teach an implant comprising ***microparticles*** of tricalcium phosphate having a specific ***surface area*** of ***0.5 to 100 m^2/g*** which are capable of ***biodegrading*** in the tissue within a period of ***2 to 36 months*** after implantation, as required by claim 38 and the claims dependent therefrom.

Furthermore, a person of ordinary skill in the art trying to make a bioresorbable implant would have no reason to look to or rely upon teachings related to permanent implants such as those described in Hubbard et al. and Janas et al. In fact, the Examiner has still not identified any reason why a person

of ordinary skill would combine the elements of Hubbard et al. and Janas et al. in a manner according to the subject matter of the instant claims.

Accordingly, for the reasons outlined above, the combination of Hubbard et al. in view of Janas et al. does not establish a *prima facie* case of obviousness against claims 38-46, 49-51 and 54, at least because each and every element of claim 38 is not taught. Therefore, the rejected claims are nonobvious within the meaning of 35 U.S.C. §103(a).

As such, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 38-46, 49-51 and 54 and remand the case back to the Examiner to issue a Notice of Allowance.

B. Rejection of claims 38, 47 and 48 under 35 U.S.C. §103(a)

Appellants respectfully submit that the rejection of the indentified claims as being obvious over Hubbard et al. in view of Janas et al. and Draenert is improper and should be reversed. Appellants respectfully submit that Hubbard et al. in view of Janas et al. and Draenert do not render Appellants' claims 38, 47 and 48 obvious for at least the following reasons.

The requirements for a successful *prima facie* case of obviousness are set out above, in Section 8. A., and are hereby incorporated by reference in their entirety.

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. nor Draenert teach or suggest every element of

the presently claimed subject matter, as required by *In re Wilson*. Likewise, whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. nor Draenert provide any indication that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*, or provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

The teachings of Hubbard et al. and Janas et al. are discussed above, in Section 8.A., and those comments are hereby incorporated by reference in their entirety.

With respect to Hubbard et al., Appellants respectfully submit that the following are the deficiencies in the teachings of Hubbard et al.:

- there is a clear teaching away from biodegradability/degradation due to the ***permanent*** nature of the implants taught therein;
- no biodegradability or time period for degradation is described for ßTCP (which is consistent with the permanence of the implants taught);
- no combinations of hyaluronic acid with a biodegradable thixotropic compound with pseudoplastic properties (such as a polysaccharide) are taught; and
- no specific surface area or overall amount of the ceramic compound is taught.

Janas et al., introduced by the Examiner to show a specific surface area, does not remedy the deficiencies of Hubbard et al. as shown above.

Draenert teaches an implantation material comprising a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture thereof, and 5-35% by weight of resorbable tricalcium phosphate. This reference is cited by the Examiner to cure the deficiency of Hubbard et al. relating to the lack of teaching of the amount of ceramic material present.

Appellants respectfully submit that even assuming *arguendo* the teachings of Draenert shows the instantly claimed amount of the microparticles, Draenert does not cure the remaining deficiencies of Hubbard et al. Specifically, Draenert teaches ***stable implantation materials***, i.e., bone cements. S*ee*, col. 1, lines 1 to 13 and col. 2, lines 23-30. The stable implantation materials taught by Draenert are used in bone replacement and bonding, as well as prosthesis anchoring materials, which are ***permanent*** structures.

Again, the instantly claimed microparticles are capable of biodegrading within a period of 2 to 36 months from implantation and are clearly not shown by this combination of references. In part, it is the large surface area of the instant microporous ceramic particles (i.e., 0.5 m^2/g to 100 m^2/g) that affords the ability of the presently claimed implant to be bioresorbable. In contrast, the particles of Hubbard et al. are smooth and non-porous, as well as round and substantially spherical. While the technologies taught in these cited references are *generally* related to the claimed subject matter, there is nothing in any of the cited references which would lead one of ordinary skill in the art to modify the

teachings of these three references relating *entirely* to permanent tissue and bone repair to arrive at the instantly claimed subject matter relating to bioresorbable implants.

Thus, the combination of Hubbard et al., in view of Janas et al. and Draenert, fails to teach an implant comprising ***microparticles*** of tricalcium phosphate having a specific ***surface area*** of ***0.5 to 100 m^2/g*** which are capable of ***biodegrading*** in the tissue within a period of ***2 to 36 months*** after implantation, as required by claims 38, 47 and 48.

Accordingly, the combination of Hubbard et al. in view of Janas et al. and Draenert does not establish a *prima facie* case of obviousness against claims 38, 47 and 48, at least because each and every element of claim 38 is not taught. Therefore, the rejected claims are nonobvious within the meaning of 35 U.S.C. §103(a).

As such, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 38, 47 and 48 and remand the case back to the Examiner to issue a Notice of Allowance.

C. Rejection of claims 38 and 51-53 under 35 U.S.C. §103(a)

Appellants respectfully submit that the rejection of the identified claims as obvious Hubbard et al. in view of Janas et al. and Gertzman et al. is improper and should be reversed. Appellants respectfully submit that Hubbard et al. in view of Janas et al. and Gertzman et al. do not render Appellants' claims 38 and 51-53 obvious for at least the following reasons.

The requirements for a successful *prima facie* case of obviousness are set out above, in Section 8. A., and are hereby incorporated by reference in their entirety.

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. nor Gertzman et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. Likewise, whether taken alone, or in combination, neither Hubbard et al. nor Janas et al. nor Gertzman et al. provide any indication that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*, or provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

The teachings of Hubbard et al. and Janas et al. are discussed above, in Section 8.A., and those comments are hereby incorporated by reference in their entirety.

With respect to Hubbard et al., Appellants respectfully submit that the following are the deficiencies in the teachings of Hubbard et al.:

- there is a clear teaching away from biodegradability/degradation due to the ***permanent*** nature of the implants taught therein;
- no biodegradability or time period for degradation is described for ßTCP (which is consistent with the permanence of the implants

taught);

- no combinations of hyaluronic acid with a biodegradable thixotropic compound with pseudoplastic properties (such as a polysaccharide) are taught; and
- no specific surface area or overall amount of the ceramic compound is taught.

Janas et al., introduced by the Examiner to show a specific surface area, does not remedy the deficiencies of Hubbard et al. as shown above.

Gertzman et al. teach a formable bone composition for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles. This reference has been cited by the Examiner as teaching sodium hyaluronate carriers for the formable bone composition having a molecular weight of $6.6X10^5$ - $2.6X10^6$.

Appellants respectfully submit that even assuming *arguendo* the teachings of Gertzman et al. show the instantly claimed molecular weight of hyaluronic acid, Gertzman et al. do not cure the remaining deficiencies of Hubbard et al. Specifically, Gertzman et al. teach ***formable bone compositions.*** The compositions taught by Gertzman et al. do not show an implant comprising βTCP which is biodegradable within 2 to 36 months of implantation. Furthermore, Gertzman et al. fails to teach the use of the hyaluronic acid compound *in combination* with a thixotropic compound (such as a xanthan-based compound or a cellulose derivative), as is instantly claimed. The instant microparticles capable

of biodegrading within a period of 2 to 36 months after implantation are clearly not shown by this combination of references. In part, it is the large surface area of the instant microporous ceramic particles (i.e., 0.5 m^2/g to 100 m^2/g) that affords the ability of the presently claimed implant to be bioresorbable. In contrast, the particles of Hubbard et al. are smooth and non-porous, as well as round and substantially spherical. While, as in the previous instances, the subject matter of the cited references *generally* relates to the claimed subject matter, there is nothing in any of the cited references which would lead one of ordinary skill in the art to modify the teachings contained therein to arrive at the instantly claimed subject matter relating to bioresorbable implants.

Thus, the combination of Hubbard et al., Janas et al. and Gertzman et al. fails to teach an implant comprising ***microparticles*** of tricalcium phosphate having a ***specific surface area*** of ***0.5 to 100 m^2/g*** which are capable of ***biodegrading*** in the tissue within a period of ***2 to 36 months*** after implantation, as required by claims 38 and 51-53.

Accordingly, the combination of Hubbard et al. in view of Janas et al. and Gertzman et al. does not establish a *prima facie* case of obviousness against claims 38 and 51-53, at least because each and every element of claim 38 is not taught. Therefore, the rejected claims are nonobvious within the meaning of 35 U.S.C. §103(a).

As such, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 38 and 51-53 and remand the case back to the Examiner to issue a Notice of Allowance.

D. Rejection of claims 55-66 and 69 under 35 U.S.C. §103(a)

Appellants respectfully submit that the rejection of the identified claims as obvious over Hubbard et al. in view of Draenert is improper and should be reversed. Appellants respectfully submit that the combination of Hubbard et al. in view of Draenert does not render Appellants' claims 55-66 and 69 obvious for at least the following reasons.

The requirements for a successful *prima facie* case of obviousness are set out above, in Section 8. A., and are hereby incorporated by reference in their entirety.

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Hubbard et al. nor Draenert teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. Likewise, whether taken alone, or in combination, neither Hubbard et al. nor Draenert provide any indication that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*, or provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

The teachings of Hubbard et al. and Draenert are discussed above, in Sections 8.A and B, respective, and those comments are hereby incorporated by reference in their entirety.

With respect to Hubbard et al., Appellants respectfully submit that the following are the deficiencies in the teachings of Hubbard et al.:

- there is a clear teaching away from biodegradability/degradation due to the ***permanent*** nature of the implants taught therein;
- no biodegradability or time period for degradation is described for ßTCP (which is consistent with the permanence of the implants taught); and
- no combinations of hyaluronic acid with a biodegradable thixotropic compound with pseudoplastic properties (such as a polysaccharide) are taught.

Furthermore, Hubbard et al. do not teach or suggest that the microparticles are present in the vector fluid in an amount "greater than 0 and less than 15%" as required by claim 55.

Draenert teaches an implantation material comprising a polymeric base of an acrylate, a polymethacrylate, a copolymer of an acrylate and a methacrylate or a mixture thereof, and 5-35% by weight of resorbable tricalcium phosphate. This reference is cited by the Examiner to cure the deficiency of Hubbard et al. relating to the lack of teaching with respect to the amount of ceramic material present.

Appellants respectfully submit that even assuming *arguendo* the teachings of Draenert shows the instantly claimed amount of the microparticles, Draenert does not cure the remaining deficiencies of Hubbard et al. Specifically, Draenert teaches ***stable implantation materials***, i.e., bone cements. S*ee*, col. 1, lines 1

to 13 and col. 2, lines 23-30. The stable implantation materials taught by Draenert are used in bone replacement and bonding, as well as prosthesis anchoring materials, which are ***permanent*** structures.

Again, the instantly claimed microparticles are capable of biodegrading within a period of 2 to 36 months from implantation and are clearly not shown by this combination of references. In contrast, the particles of Hubbard et al. are smooth and non-porous, as well as round and substantially spherical. While the technologies taught in these cited references are *generally* related to the claimed subject matter, there is nothing in either of the cited references which would lead one of ordinary skill in the art to modify the teachings of these two references relating *entirely* to permanent tissue and bone repair to arrive at the instantly claimed subject matter relating to bioresorbable implants.

Thus, the combination of Hubbard et al., in view of Draenert fails to teach an implant comprising ***microparticles*** of tricalcium phosphate which are capable of ***biodegrading*** in the tissue within a period of ***2 to 36 months*** after implantation, as required by claims 55-66 and 69.

Accordingly, the combination of Hubbard et al. in view of Draenert does not establish a *prima facie* case of obviousness against claims 55-66 and 69, at least because each and every element of claim 55 is not taught. Therefore, the rejected claims are nonobvious within the meaning of 35 U.S.C. §103(a).

As such, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 55-66 and 69 and remand the case back to the Examiner to issue a Notice of Allowance.

E. Rejection of claims 55 and 66-68 under 35 U.S.C. §103(a)

Appellants respectfully submit that the rejection of the identified claims as obvious over Hubbard et al. in view of Gertzman et al. is improper and should be reversed. Appellants respectfully submit that Hubbard et al. in view of Gertzman et al. do not render Appellants' claims 55 and 66-68 obvious for at least the following reasons.

The requirements for a successful *prima facie* case of obviousness are set out above, in Section 8. A., and are hereby incorporated by reference in their entirety.

Appellants submit that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Hubbard et al. nor Gertzman et al. teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. Likewise, neither Hubbard et al. nor Gertzman et al. indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*, or provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

The teachings of Hubbard et al. and Gertzman et al. are discussed above, in Sections 8.A and B, respectively, and those comments are hereby incorporated by reference in their entirety.

With respect to Hubbard et al., Appellants respectfully submit that the following are the deficiencies in the teachings of Hubbard et al.:

- there is a clear teaching away from biodegradability/degradation due to the ***permanent*** nature of the implants taught therein;
- no biodegradability or time period for degradation is described for ßTCP (which is consistent with the permanence of the implants taught); and
- no combinations of hyaluronic acid with a biodegradable thixotropic compound with pseudoplastic properties (such as a polysaccharide) are taught.

Furthermore, Hubbard et al. do not teach or suggest that the microparticles are present in the vector fluid in an amount "greater than 0 and less than 15%" as required by claim 55.

Gertzman et al. teach a formable bone composition for application to a bone defect site to promote new bone growth at the site which comprises a new bone growth inducing compound of demineralized lyophilized allograft bone particles. This reference has been cited by the Examiner as teaching sodium hyaluronate carriers for the formable bone composition having a molecular weight of $6.6X10^5$ - $2.6X10^6$.

Appellants respectfully submit that even assuming *arguendo* the teachings of Gertzman et al. show the instantly claimed molecular weight of hyaluronic acid, Gertzman et al. do not cure the remaining deficiencies of Hubbard et al. Specifically, Gertzman et al. teach ***formable bone compositions.*** The

compositions taught by Gertzman et al. do not show an implant comprising βTCP which is biodegradable in within 2 to 36 months of implantation. Furthermore, Gertzman et al. fails to teach the use of the hyaluronic acid compound *in combination* with a thixotropic compound (such as a xanthan-based compound or a cellulose derivative), as instantly claimed. The instant microparticles capable of biodegrading within a period of 2 to 36 months after implantation are clearly not shown by this combination of references. In contrast, the particles of Hubbard et al. are smooth and non-porous, as well as round and substantially spherical. While, as in the previous instances, the subject matter of the cited references *generally* relates to the claimed subject matter, there is nothing in any of the cited references which would lead one of ordinary skill in the art to modify the teachings contained therein to arrive at the instantly claimed subject matter relating to bioresorbable implants.

Thus, the combination of Hubbard et al., and Gertzman et al. fail to teach an implant comprising ***microparticles*** of tricalcium phosphate which are capable of ***biodegrading*** in the tissue within a period of ***2 to 36 months*** after implantation, as required by claims 55 and 66-68.

Accordingly, the combination of Hubbard et al. in view of Gertzman et al. does not establish a *prima facie* case of obviousness against claims 55 and 66-68, at least because each and every element of claim 55 is not taught. Therefore, the rejected claims are nonobvious within the meaning of 35 U.S.C. §103(a).

As such, Appellants respectfully request the Board of Patent Appeals and Interferences to reverse the present rejection of pending claims 55 and 66-68 and remand the case back to the Examiner to issue a Notice of Allowance.

In view of the foregoing, Appellants respectfully request the reversal of the Examiner's rejections and the allowance of the pending claims. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 14-0112.

Respectfully submitted,

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Date: February 22, 2011

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9. Appendix A

1-33. (Canceled)

34. (Withdrawn) A process for preparing an injectable implant for subcutaneous or intradermal injection into fibrous tissue, said implant comprising microparticles of at least one biocompatible ceramic compound in suspension in at least one vector fluid, said implant being such that said microparticles are biodegradable and have a size of from 10 to 80 μm, said ceramic compound comprising at least one component chosen from the group formed by tricalcium phosphate (βTCP) and biphasic products (BPC) which comprise HAP and βTCP in variable proportion, and in that said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties, wherein said process comprises the following steps: a biocompatible ceramic compound in the form of microparticles is prepared in a first step, in an other step, independently or not of the above preliminary step, a solution of a vector fluid comprising at least one hyaluronic acid-based compound and at least one biodegradable thixotropic compound with pseudoplastic properties is prepared, the ceramic compound from the first step is then introduced into the vector fluid from the other step, in a final step, so as to obtain an essentially homogeneous suspension.

35. (Cancelled)

36. (Withdrawn) A kit for the extemporaneous use of an implant as claimed in claim 38 or as claimed claim 17, wherein the kit comprises a ceramic compound in a first part and a vector fluid in a second part.

37. (Withdrawn) A process for filling wrinkles and/or fine lines and/or skin depressions and/or scars, comprising the subcutaneous injection of an implant as claimed in claim 14 or as claimed claim 17.

38. (Previously Presented) A resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid,

wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months and have a size of from 10 to 80 μm, said ceramic compound is tricalcium phosphate (βTCP) and has a specific surface area of from 0.5 m^2/g to 100 m^2/g, and said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties.

39. (Previously Presented) The implant according to claim 38 wherein said microparticles have a size of from 15 to 50 μm.

40. (Previously Presented) The implant according to claim 38 wherein said vector fluid comprises at least one thixotropic compound with pseudoplastic properties based on xanthan gum.

41. (Previously Presented) The implant according to claim 38 wherein said vector fluid comprises at least one thixotropic compound with pseudoplastic properties based on cellulose derivatives.

42. (Previously Presented) The implant according to claim 41 wherein the cellulose derivatives are selected from the group consisting of carboxymethyl cellulose (CMC), hydroxypropylmethyl cellulose (HPMC) and hydroxypropyl cellulose (HPC).

43. (Previously Presented) The implant according to claim 42 wherein the cellulose derivative is a carboxymethyl cellulose (CMC).

44. (Previously Presented) The implant according to claim 38 wherein said ceramic compound has a specific surface area of from 2 m^2/g to 27 m^2/g.

45. (Previously Presented) The implant according to claim 38 wherein the microparticles are bioresorbable, once the implantation has been made into a fibrous tissue, within a period of from 3 to 24 months.

46. (Previously Presented) The implant according to claim 45 wherein the microparticles are bioresorbable, once the implantation has been made into a fibrous tissue, within a period of from 4 to 18 months.

47. (Previously Presented) The implant according to claim 38 wherein the microparticles are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%.

48. (Previously Presented) The implant according to claim 38 wherein the microparticles are present in the vector fluid in a weight/volume proportion from 2% to 12%.

49. (Previously Presented) The implant according to claim 38 wherein the vector fluid for the implant is a biocompatible gel.

50. (Previously Presented) The implant according to claim 38 wherein the vector fluid for the implant is a bioresorbable gel.

51. (Previously Presented) The implant according to claim 38 wherein the hyaluronic acid-based compound predominantly comprises hyaluronic acid.

52. (Previously Presented) The implant according to claim 51 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of greater than one million daltons.

53. (Previously Presented) The implant according to claim 52 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of from one million to five million daltons.

54. (Previously Presented) The implant according to claim 38, wherein said implant is in the form of a ready-to-use prefilled syringe, a ready-to-use prefilled bottle or a lyophilizate to be reconstituted.

55. (Previously Presented) A resorbable implant for subcutaneous or intradermal injection into fibrous tissue, comprising microparticles of one biocompatible ceramic compound in suspension in at least one vector fluid,

wherein said microparticles are biodegradable, once the implantation has been made into the fibrous tissue, within a period of from 2 to 36 months, have a size of from 10 to 80 μm, and are present in the vector fluid in a weight/volume proportion strictly greater than 0% and less than 15%,

said ceramic compound is tricalcium phosphate (βTCP), and

said vector fluid comprises at least one compound based on hyaluronic acid and at least one biodegradable thixotropic compound with pseudoplastic properties.

56. (Previously Presented) The implant according to claim 55 wherein the microparticles are present in the vector fluid in a weight/volume proportion from 2% to 12%.

57. (Previously Presented) The implant according to claim 55 wherein said microparticles have a size of from 15 to 50 μm.

58. (Previously Presented) The implant according to claim 55 wherein said vector fluid comprises at least one thixotropic compound with pseudoplastic properties based on xanthan gum.

59. (Previously Presented) The implant according to claim 55 wherein said vector fluid comprises at least one thixotropic compound with pseudoplastic properties based on cellulose derivatives.

60. (Previously Presented)The implant according to claim 59 wherein the cellulose derivatives are selected from the group consisting of carboxymethyl cellulose (CMC), hydroxypropylmethyl cellulose (HPMC) and hydroxypropyl cellulose (HPC).

61. (Previously Presented) The implant according to claim 60 wherein the cellulose derivative is a carboxymethyl cellulose (CMC).

62. (Previously Presented) The implant according to claim 55 wherein the microparticles are bioresorbable, once the implantation has been made into a fibrous tissue, within a period of from 3 to 24 months.

63. (Previously Presented) The implant according to claim 62 wherein the microparticles are bioresorbable, once the implantation has been made into a fibrous tissue, within a period of from 4 to 18 months.

64. (Previously Presented) The implant according to claim 55 wherein the vector fluid for the implant is a biocompatible gel.

65. (Previously Presented) The implant according to claim 55 wherein the vector fluid for the implant is a bioresorbable gel.

66. (Previously Presented) The implant according to claim 55 wherein the hyaluronic acid-based compound predominantly comprises hyaluronic acid.

67. (Previously Presented) The implant according to claim 66 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of greater than one million daltons.

68. (Previously Presented) The implant according to claim 67 wherein said hyaluronic acid-based compound comprises hyaluronic acid with a molecular weight of from one million to five million daltons.

69. (Previously Presented) The implant according to claim 55, wherein said implant is in the form of a ready-to-use prefilled syringe, a ready-to-use prefilled bottle or a lyophilizate to be reconstituted.

10. Evidence Appendix

No information is appended under this section.

11. Related Proceedings Appendix

No information is appended under this section.